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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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10

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/391,783	Applicant(s) Baldwin et al.
Examiner G. Hsu, Ph.D., J.D.	Art Unit 1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jan 10, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 4-7 and 38-49 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 4-7 and 38 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s).
16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 20) Other:

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DETAILED ACTION

1. An Amendment Under 37 C.F.R. § 1.111 received on January 10, 2001 was entered as Paper No. 9.

Status of Claims

2. Claims 4-7 and 38-49 (claims 39-49 are newly added) are pending and under examination in the current application.
3. Claims 1-3 and 8-37 were canceled by applicants' September 8, 1999 and January 10, 2001 requests.

Response to January 10, 2001 Amendment

4. This Office Action is in response to the January 10, 2001 Amendment.
5. For the record, it is noted that applicants': [1] have received October 16, 2000 action on the merits for the originally claimed invention; and that [2] arguments as set forth in applicants' January 10, 2000 Amendment have been directed to the claims **as amended** and not to the claims as originally presented for examination in the October 16, 2000 Office Action.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objection(s) and/or Rejection(s)

7. The objections of Claims 5-7 for typographical errors are withdrawn in light of applicants' amendments.

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8. The following rejection of claims 4-7 and 38 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in light of applicants' arguments.

Outstanding Objection(s) and/or Rejection(s)

9. **For the record it is noted that the October 16, 2000 Office Action included an inadvertant error, wherein only claim 4 was rejected over the prior art as set forth below, when the Examiner intended that claims 4-7 and 38 be rejected over the prior art as set forth below.**

For the sake of clarification, the reiterated rejections below further note specific element(s) taught by corresponding each reference, which is/are more clearly set forth below in bolded text for applicants convenience.

10. The rejection of claims 4-7 and 38 is rejected under 35 U.S.C. 102(b) as being anticipated by Jennings (J. Chem. Soc. Perkin Trans., 1984, page 1733-1738) is **maintained for the following reasons of record.**

The claimed invention is directed to a substituted dihydrobenzopyran compound of formula (II), wherein the following functional group variables are substituted on different positions of the bicyclic fused ring core, wherein the pyran portion of that core is substituted with an oxygen atom at the 1-position, "R⁴" and "R⁵" at the 2-position, and "R⁶" and "R⁷" at the 4-position, while the benzo portion of the ring core at any one of positions 5-8 may be substituted with "R¹" and "R²", wherein each of the aforementioned variables are respectively defined in the claims and/or instant specification.

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Jennings discloses: [1] a dihydrobenzopyran compounds and corresponding derivatives that anticipate the compounds of the claimed invention; [2] wherein the aforementioned compounds have functional group substituents that are anticipated and correspond to the R¹, R², R⁴-R⁷ functional group substituents on the dihydrobenzopyran ring core of the claimed invention; and [3] for example compound species that anticipate the claimed compounds are substituted with following corresponding groups, wherein: [a] R¹ is either hydroxy or methoxy and or R² is hydrogen (**also viceversa, see page 1733, col. 2, line 27, i.e., compound (20), wherein R1 =R3 =OH, R2 = R4 =H**) ; R⁴ = R⁵ = methyl, R⁶ and R⁷ taken together = “C=O”(see, page 1735, col. 1, Compounds 24 and 25).

Therefore, Jennings anticipates the claimed invention.

In the January 10, 2001 Amendment, applicants assert that:

- [1] Jennings et al. does not disclose compounds encompassed by the claimed invention;
- [2] that the above-identified rejection relies upon compounds 24 and 25 of Jennings et al., wherein it is “point[ed] out that the [structure 24 recited therein] would require one of the R¹ or R² of applicants’ formula II to be a methoxy [group], a choice not claimed by applicants [instant invention]”; and
- [3] in light of the foregoing, requests that the instant rejection be withdrawn.

In response, it is the position of the Examiner that:

- [1] applicants arguments have been carefully considered, but not found not persuasive for the following reasons:

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[2] Jennings et al. does discloses a compound of the claimed invention, when review in light the above identified rejection (see bolded text) and the instant reference at **page 1733, col. 2, line 27, i.e., which defines a compound, wherein $R^1 = R^3 = OH$, $R^2 = R^4 = H$;**

[3] **In light of the foregoing, the rejection of record is maintained and deemed proper.**

11. The rejection of claims 4-7 and 38 under 35 U.S.C. 102(b) as being anticipated by EP Patent Application No.: 0 415 566 A1, Publication Date: March 6, 1991 are maintained for the following reasons of record.

EP Appln. No. 0 415 566 A1 discloses: [1] a dihydrobenzopyran compounds and corresponding derivatives that anticipate the compounds of the claimed invention; [2] wherein the aforementioned compounds have functional group substituents that are anticipated and correspond to the R^1 , R^2 , R^4 - R^7 functional group substituents on the dihydrobenzopyran ring core of the claimed invention; and [3] example compound species that anticipate the claimed compounds are substituted with the following groups, wherein. [a] Y is O, R^1 and R^2 (**as recited in the instant EP appln., which corresponds to R^4 and R^5 of the claimed invention**) are independently **hydrogen, lower alkyl**, phenyl or substituted phenyl, R^3 is hydrogen (**which corresponds to the methylene, i.e., CH_2 group adjacent to the R^6 and R^7 groups of the claimed invention**), B is a C=O (which corresponds to R^6 and R^7 of the claimed invention), R^4 is **a hydrogen, OR⁵, wherein R⁵ is H or lower alkyl** (which corresponds to **R² of the claimed invention**) and “ R^7 OCO-A-Z”, wherein Z is oxygen, A is a straight or branched hydrocarbon

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radical having one to five carbon atoms, and R⁷ (R⁷ recited therein is distinguished from R⁷ of the claimed invention; note that the group "**R⁷OCO-A-Z**" corresponds to R¹ of the claimed invention, wherein R¹ is O-(CH₂)CO₂H.

Therefore, EP Appln. No. 0 415 566 A1 anticipates the claimed invention.

In the January 10, 2001 Amendment, applicants assert that:

- [1] EP Appln. No. 0 415 566 A1 does not disclose or anticipate compounds encompassed by the claimed invention;
- [2] in light of the foregoing, requests that the instant rejection be withdrawn.

In response, it is the position of the Examiner that:

- [1] applicants arguments have been carefully considered, but not found not persuasive for the following reasons:
- [2] EP Appln. No. 0 415 566 A1 does discloses a compound of the claimed invention, when review in light the above identified rejection, wherein:
 - [a] Y is O, R¹ and R² (**as recited in the instant EP appln., which corresponds to R⁴ and R⁵ of the claimed invention**) are independently hydrogen, lower alkyl, phenyl or substituted phenyl;
 - [b] R³ is hydrogen (**which corresponds to the methylene, i.e., CH₂ group adjacent to the R⁶ and R⁷ groups of the claimed invention**);
 - [c] B is a C=O (which corresponds to R⁶ and R⁷ of the claimed invention);

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- [d] R^4 is a hydrogen, OR^5 , wherein R^5 is H or lower alkyl (**which corresponds to R^2 of the claimed invention**);
- [e] R^6 is a hydrogen or lower alkyl (which corresponds to **R^2 of the claimed invention**) and " R^7 OCO-A-Z", wherein Z is oxygen, A is a straight or branched hydrocarbon radical having one to five carbon atoms; and
- [f] R^7 (R^7 recited therein is distinguished from R^7 of the claimed invention; note that the group " **R^7 OCO-A-Z**" **corresponds to R^1** of the claimed invention, wherein **R^1 is $O-(CH_2)CO_2H$** ; and
- [g] see, also compounds V, at page 3, lines 45-50 and compound VI at page 4, lines 40-45, compound I' at page 6, lines 20-25, etc.

[3] **In light of the foregoing, the rejection of record is maintained and deemed proper.**

12. The rejection of claims 4-7 and 38 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,268,386 (herein referred to as "the U.S. '386 Patent", Issued: December 7, 1983, Filed July 26, 1990 are maintained for the following reasons of record.

The U.S. '386 Patent discloses: [1] a dihydrobenzopyran compounds and corresponding derivatives that anticipate the compounds of the claimed invention; [2] wherein the aforementioned compounds have functional group substituents that are anticipated and correspond to the R^1 , R^2 , R^4 - R^7 functional group substituents on the dihydrobenzopyran ring core of the claimed invention; and [3] example compound species that anticipate the claimed

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compounds are substituted with the following groups, wherein: [a] Y is O, R1 and R2 are independently hydrogen, lower alkyl, phenyl or substituted phenyl (which corresponds to R4 and R5 of the claimed invention), R3 is hydrogen, B is a C=O (which corresponds to R6 and R7 of the claimed invention), R6 is a hydrogen or lower alkyl (which corresponds to R2 of the claimed invention) and “R⁷OCO-A-Z”, wherein Z is oxygen, A is a straight or branched hydrocarbon radical having one to five carbon atoms, and R7 (R7 recited therein is distinguished from R7 of the claimed invention; note that the group “R⁷OCO-A-Z” corresponds to R1 of the claimed invention, wherein R1 is O-(CH₂)CO₂H is hydrogen.

Therefore, the U.S. '386 Patent anticipates the claimed invention.

In the January 10, 2001 Amendment, applicants assert that:

- [1] the U.S. '386 Patent A1 does not disclose or anticipate compounds encompassed by the claimed invention;
- [2] in light of the foregoing, requests that the instant rejection be withdrawn.

In response, it is the position of the Examiner that:

- [1] applicants arguments have been carefully considered, but not found not persuasive for the following reasons:
- [2] U.S. '386 Patent does discloses a compound of the claimed invention, when review in light the above identified rejection, wherein:
 - [a] Y is O, R¹ and R² (**as recited in the instant EP appln., which corresponds to R⁴ and R⁵ of the claimed invention**) are independently **hydrogen, lower alkyl, phenyl or substituted phenyl**;

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- [b] R^3 is hydrogen (which corresponds to the methylene, i.e., CH_2 group adjacent to the R^6 and R^7 groups of the claimed invention);
- [c] B is a C=O (which corresponds to R^6 and R^7 of the claimed invention);
- [d] R^4 is a hydrogen, OR⁵, wherein R⁵ is H or lower alkyl (which corresponds to R^2 of the claimed invention);
- [e] R^6 is a hydrogen or lower alkyl (which corresponds to R^2 of the claimed invention) and “ R^7 OCO-A-Z”, wherein Z is oxygen, A is a straight or branched hydrocarbon radical having one to five carbon atoms; and
- [f] R^7 (R^7 recited therein is distinguished from R^7 of the claimed invention; note that the group “ R^7 OCO-A-Z” corresponds to R^1 of the claimed invention, wherein R^1 is O-(CH_2)CO₂H; and
- [g] see, also compounds V and VI at col. 4, lines 41-60, etc.

[3] **In light of the foregoing, the rejection of record is maintained and deemed proper.**

*New Grounds of Rejection**Double Patenting*

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 4-7 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Baldwin et al., claims 1-2 of U. S. Patent No. 6,017,768 (herein referred to as the U.S. '768 Patent), Issued: January 25, 2000, Filed: October 18, 1996.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the U.S. '768 Patent and the instant application are directed to dihydrobenzopyran compounds of Formula (II), wherein those compounds have functional group variables substituted on different positions of a bicyclic fused ring core, wherein the pyran portion of that core is substituted with an oxygen atom at the 1-position, "R⁴" and "R⁵" at the 2-position, and "R⁶" and "R⁷" at the 4-position, while the benzo portion of the ring core at any one of positions 5-8 may be substituted with "R¹" and "R²"; and/or [2] the use of the aforementioned compounds in as part of a combinatorial library as taught by the U.S. '768 Patent.

The U.S. '768 Patent claims combinatorial libraries that contain dihydrobenzopyran compounds of the same formula as that of the claimed invention, wherein those compounds have functional group variables substituted on different positions of a bicyclic fused ring core, wherein

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the pyran portion of that core is substituted with an oxygen atom at the 1-position, "R⁴" and "R⁵" at the 2-position, and "R⁶" and "R⁷" at the 4-position, while the benzo portion of the ring core at any one of positions 5-8 may be substituted with "R¹" and "R²."

In view of the above, the instant claims differ from: the U.S. '768 Patent in that it does not specifically claim the use of the aforementioned compounds as part of combinatorial libraries.

However, the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the compounds claimed in the instant invention are disclosed and part of the combinatorial libraries of the claims of the U.S. '768 Patent.

A person of ordinary skill in the art would have been motivated to develop: the compounds of the instant application, because combinatorial libraries containing dihydrobenzopyran compounds of the same formula (II) are taught by the '768 Patent.

In light of the foregoing, a person of ordinary skill in the art would have had a reasonable expectation of success in developing such compounds, because combinatorial libraries containing dihydrobenzopyran compounds of the same formula (II) are taught by the '768 Patent.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the teachings of the instant application in view of the teachings of the '768 Patent.

Status of Claims

15. No claims are allowed in the above-identified application.

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Conclusion

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Grace C. Hsu, Ph.D., J.D. whose telephone number is (703) 308-7005. The Examiner may be reached during normal business hours, Monday through Friday from 8:30 am to 5:30 pm (EST). A message may be left on the Examiner's voice mail.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jythosna Venkat, Ph.D., may be reached at (703) 308-2439. The fax number assigned to Group 1627 is (703) 305-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1627 receptionist whose telephone number is (703) 308-0196.

Grace C. Hsu, Ph.D., J.D.

May 19, 2001

BENNETT CELSA
PPO EXAMINER

Grace C. Hsu